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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,255	05/23/2005	Jean Fioramonti	045636-5081	1258
9629 7590 01/12/2007 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER TONGUE, LAKIA J	
			ART UNIT	PAPER NUMBER
			1645	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/509,255	Applicant(s) FIORAMONTI ET AL.	
	Examiner Lakia J. Tongue	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,7,10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on November 14, 2006 is acknowledged. Claims 6, 7, 10, and 11 are pending. Claims 1-5, 8, 9, and 12-18 are canceled. Claims 6, 7, 10, and 11 are under examination.

After careful review of the record, the finality of the rejection of the last Office action is withdrawn.

Rejections Withdrawn

1. In view of applicants' cancellation of claims 15-18 the rejection of claims 15-18 under 35 U.S.C. 102(e) as being anticipated by Ubbink et al (U.S. 2005/0153018 A1) is withdrawn.

New Grounds of Rejection

Claim Objections

2. Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As written claim 10 does not further limit claim 7 as the list of diseases (i.e. enteritis, Crohn's disease, hemorrhagic rectocolitis, and irritable bowel syndrome) does not further limit the term pathology.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 6, 7, 10, and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating colonic inflammation due to colitis comprising administering an effective amount of a composition comprising lactic acid bacteria of the species *Lactobacillus farciminis*, does not reasonably provide enablement for any method of treating colonic inflammation and/or colonic hypersensitivity to distention due to any other pathology. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the

Art Unit: 1645

nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CRFC1988). The Wands factors have been considered in the establishment of this scope of enablement rejection. These factors include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instant claims are drawn to a method of treating colonic inflammation and/or colonic hypersensitivity to distention due to any acute or chronic inflammatory pathology (e.g. Crohn's disease, hemorrhagic rectocolitis, irritable bowel syndrome), said method comprising administering an effective amount of a composition comprising lactic acid bacterium of the species *Lactobacillus farciminis*.

Breadth of the claims: The claims are broadly drawn and encompass administering *Lactobacillus farciminis* to a subject to treat colonic hypersensitivity to distention due to any pathology.

Direction or guidance presented in the specification: The specification does not provide substantive evidence that the claimed composition is capable of treating colonic hypersensitivity to distention due to any pathology other than colitis. This demonstration is required for the skilled artisan to be able to use the claimed composition for their intended purpose of treating said maladies. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the claimed method. The instant specification speaks to a method of treating colonic inflammation due to colitis comprising administering an effective amount of a composition comprising lactic acid bacterium of the species *Lactobacillus farciminis*. However, the specification does not provide any correlation between the animal data shown (animal model for colitis) and other etiologies or diseases. There is insufficient direction or guidance presented in the specification with regard to treating colonic inflammation and/or colonic hypersensitivity to distention generally, or wherein the cause is any acute or chronic inflammatory pathology (e.g. enteritis, Crohn's disease, hemorrhagic rectocolitis, and irritable bowel syndrome) utilizing a composition comprising lactic acid bacteria of the species *Lactobacillus farciminis*.

Presence or absence of working examples: There are no working examples, which suggest treating colonic inflammation and/or colonic hypersensitivity to distention

due to any pathology other than colitis utilizing a composition comprising lactic acid bacteria of the species *Lactobacillus farciminis*.

State of the prior art: The prior art provides no guidance with regard to the use of lactobacilli to treat colonic inflammation and/or colonic hypersensitivity to distention. Moreover, the art teaches that there are several options to treating inflammatory diseases like irritable bowel syndrome (IBS), colonic inflammation and ulcerative colitis.

HealingWithNutrition.com

(see <http://www.HealingWithNutrition.com/iddisease/inflam bowel/chrohns.html>) discloses that treatment for Crohn's disease depends on the location and severity of the disease, complications and response to previous treatments. The goals of treatment are to control inflammation, correct nutritional deficiencies and relieve symptoms like abdominal pain, diarrhea and rectal bleeding (see page 4).

InteliHealth (<http://www.intelihealth.com/IH/ihIH/WSIHW000/9339/10208.html>, October 23, 2005) discloses that there is no single test to offer a definite diagnosis of IBS. Additionally it is stated that a person may be able to reduce the frequency and severity of symptoms by reducing stress or changing the diet (see page 2).

Quantity of experimentation necessary: The quantity of experimentation necessary would be undue as no relevant evidence has been made of record establishing the amount of experimentation necessary. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use the claimed genus. In view of the

Art Unit: 1645

above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

4. Claim 6, 7, 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is rendered vague and indefinite by the use of the term "bacterium". The claims are drawn to the application of a single organism, as the term bacterium is the singular form of bacteria. Moreover, the composition comprises bacteria of the species *Lactobacillus farciminis*. As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 7 is rendered vague and indefinite by the use of the phrase "chronic inflammatory pathology of the intestine". It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. What constitutes a "chronic inflammatory pathology of the intestine"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Conclusion


5. No claim is allowed.


Art Unit: 1645

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


LJT.
12/27/06


ROBERT A. ZEMAN
PRIMARY EXAMINER